

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Yves Auberson

Title: COUMARINES USEFUL AS BIOMARKERS

Appl. No.: 10/506,381

International Filing Date: March 5, 2003

371 (c) Date: September 2, 2004

Patent No.: 7,569,337

Grant Date: August 4, 2009

Examiner: Ebenezer O. Sackey

Art Unit: 1624

Confirmation Number: 1643

**SECOND REQUEST FOR RECONSIDERATION OF PATENT TERM
ADJUSTMENT UNDER 37 C.F.R. § 1.705**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicant respectfully requests reconsideration of the DECISION ON APPLICATION FOR PATENT TERM ADJUSTMENT (“Decision”), dated December 22, 2009, dismissing Applicant’s REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705” (“First Request”), which was filed on October 2, 2009.

Applicant filed the First Request requesting reconsideration of the Patent Term Adjustment (“PTA”) determined for the captioned patent, which issued on August 4, 2009 as

United States Patent number 7,569,337. According to the Decision by the U.S. Patent and Trademark Office (“Office”) dismissing the First Request, “[t]he Office contends that all 698 days for over three year pendency overlap with the 727 days accorded for Office delay during the pendency of the application, and thus, no additional days were entered for over three year delay.”

See Decision at page 2. The Office further states:

Patentees’ calculation of the period of overlap is inconsistent with the Office’s interpretation of this provision. 35 U.S.C. 154(b)(2)(A) limits the adjustment of patent term, as follows:

[T]o the extent that the periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

Likewise, 35 CFR 1.703(f) provides that:

To the extent that periods of delay attributable to the grounds specified in § 1.702 overlap, the period of adjustment granted under this section shall not exceed the actual number of days the issuance of the patent was delayed.

Id.

On January 7, 2010, the U.S. Court of Appeals for the Federal Circuit upheld the District Court’s decision and determined that the statute as written by Congress has been misinterpreted by the USPTO. *Wyeth v. Kappos*, --- F.3d ----, 2010 WL 27184 (Dist.Col. 2010). Accordingly, Applicant is submitting this SECOND REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705.

The Patent Office determined that the patent was entitled to 640 days of PTA. According to the Decision, this PTA determination was made in accordance with the “Explanation of 37 C.F.R. § 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. §154(b)(2)(A)” published at 69 Fed. Reg. 34238 (Jun. 21, 2004). *See* Decision at page 2. Under that interpretation of the PTA statute, any PTO delay under 35 U.S.C. § 154(b)(1)(A) is deemed to overlap with any 3-year maximum pendency delay under 35 U.S.C. § 154(b)(1)(B), and so, as a practical effect, PTA may be awarded under §154(b)(1)(A) or §154(b)(1)(B), but not both.

On September 30, 2008, the United States District Court for the District of Columbia issued a decision finding that the U.S. Patent and Trademark Office’s interpretation of the PTA statute is incorrect. *Wyeth v. Dudas*, 580 F.Supp.2d 138 (D.D.C., 2008). The court determined that, under the correct interpretation of the PTA statute, periods of “overlap” are limited to “periods of time ... [that] occur on the same day.” *Wyeth* at 141. Thus, a PTO delay under § 154(b)(1)(A) overlaps with a delay under § 154(b)(1)(B) only if the delays “occur on the same day.” *Id.*

On January 7, 2010, the U.S. Court of Appeals for the Federal Circuit upheld the District Court’s decision and determined that the statute as written by Congress has been misinterpreted by the USPTO. *Wyeth v. Kappos*, --- F.3d ---, 2010 WL 27184 (Dist.Col. 2010). In its decision, the Federal Circuit agreed with Wyeth’s interpretation of delay overlap and held that calculation of PTA for issued patents is the sum of A Delay and B Delay. In interpreting the PTA statutes, the Federal Circuit stated that no ambiguity exists in the statutory language and found that

“[e]ach period of delay has its own discrete time span with clearly defined boundaries.” *Wyeth*, slip op. at 7, 8. Specifically, the Court determined that the period of B Delay begins three years after a patent application is filed and ends when the application is issued. Accordingly, “[i]f an A Delay occurs on one day and a B Delay occurs on a different day, those two days do not overlap under section 154(b)(2).” *Id.* at 8.

In addition, the U.S. Patent and Trademark Office has stated that it will not seek further review of the Federal Circuit’s *Wyeth v. Kappos* decision.

Applicant has recalculated PTA for the captioned patent under the court’s interpretation of the PTA statute, and has determined that the patent is entitled to 1257 days PTA, as shown below, which shows the relevant delays under 37 CFR §§ 1.702(a) and (b), and under 37 CFR §§ 1.703(a) and (b).

The ‘381 application was filed on September 2, 2004 and issued as the ‘337 patent on August 4, 2009.

Under 35 U.S.C. § 154(b)(1)(A), the following periods of time are attributable to PTO examination delay:

- a. A period of 642 days under 35 U.S.C. § 154(b)(1)(A)(i) due to failure by the PTO to mail an action under 35 U.S.C. § 132 not later than 14 months after the actual filing date of the application (*i.e.*, by November 2, 2005). The 642 day period corresponds to the period from November 2, 2005 (*i.e.*, when the 14 Month Delay began) to August 6, 2007 (*i.e.*, when

a first action under 35 U.S.C. § 132 - a Restriction Requirement - was mailed to Applicant).

b. A period of 89 days under 35 U.S.C. § 154(b)(1)(A)(ii) due to the failure by the PTO to mail a Non-Final Office Action not later than 4 months after applicants submitted a response to a previous action (“4 Month Examination Delay”). The 89 day period corresponds to the period from March 2, 2008 (*i.e.*, 4 Months after the Response to the Restriction Requirement was submitted to the PTO) to May 30, 2008 (*i.e.*, when a non-final Office Action was mailed to Applicant).

c. Thus, the total period of PTO examination delay under 35 U.S.C. § 154(b)(1)(A) is 731 days, which is the period of 14 Month Delay (*i.e.*, 642 days) and the period of 4 Month Examination Delay (*i.e.*, 89 days).

Under 35 U.S.C. § 154(b)(1)(B), the plaintiffs are entitled to an additional adjustment of the term of the ‘337 patent of a period of 702 days, which is the number of days the issue date of the ‘337 patent exceeds three years from the filing date of the application (“Three Year Delay”). This period corresponds to the period of time from September 2, 2007 (*i.e.*, three years after the filing date) to August 4, 2009 (*i.e.*, the patent grant date).

35 U.S.C. § 154(b)(2)(A) states that “to the extent . . . periods of delay attributable to grounds specified in paragraph [154(b)(1)] overlap, the period of any adjustment granted under this subsections shall not exceed the actual number of days the issuance of the patent was delayed.” Of the delays attributable to the PTO for the ‘337 patent, only the 89 day period of the

4 Month Examination Delay from March 2, 2008 to May 30, 2008 overlap with the Three Year Delay period (September 2, 2007 to August 4, 2009). This overlapping period is not included in the adjustment sought by Patentee.

Thus, the total period of PTA delay is 1344 days, which is the sum of the period of PTO examination delay (731 days) and the period of the Three Year Delay (702 days) reduced by the period of overlap (89 days).

Under 35 U.S.C. § 154(b)(2)(C), the total period of PTA delay is reduced by the period of applicant delay, which is 87 days as determined by the PTO. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154(b)(1) and (2) is 1257 days, which is the difference between the total period of PTA delay (1344 days) and the period of applicant delay (87 days).

To summarize:

(a) Total of non-overlapping PTO delay under § 154(b)(1)(A) & (B): 1344 days

(b) Total Applicant delay: 87 days

Final PTA Determination: **1257 days**.

Applicant therefore respectfully requests that the patent be accorded 1257 days PTA.

The attached Patent Term Adjustment Calculation System sheet (Exhibit A), which was submitted with the First Request prepared by previous counsel, inadvertently started the calculation of PTA from September 6, 2004 and not the filing date of September 2, 2004. Therefore, the calculated request of 1249 days PTA submitted in the First Request was incorrect by eight fewer days.

The patent is not subject to a terminal disclaimer.

Payment of the requisite fee was submitted with the First Request. Therefore, no fee is believed due with this submission. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-5071.

However, because this PTA error is due to a Patent Office error in interpreting and applying the PTA statute, a refund of the fee is respectfully requested.

Respectfully submitted

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EXHIBIT A